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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	20

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/300,482	Applicant(s) CHEIKH ET AL.	
	Examiner Marjorie Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *3-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) ✓
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,19* . ✓
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Reopen Prosecution

In view of the appeal brief filed on 5/1/02, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

In view of the new grounds of rejection, the finality of the previous office action is hereby withdrawn. A nonfinal action on the merits of claims 1, 2, and 10-21 follows. All rejections and objections not reiterated below are hereby withdrawn.

Election/Restrictions

This application contains claims 3-9 drawn to an invention nonelected with traverse in Paper No. 10/6/00. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Applicant is reminded that withdrawn claims are still pending claims, and is advised that the Status of the Claims set forth in the Appeal Brief is incorrect.

Priority

The response filed 9/27/01 points to support in Provisional Application 60/083,390 for sequences represented by instant SEQ ID NO's 1, 225, and 619, therefore claims 12, 16, and 21, which recite only these sequences, are accorded priority to the filing date of the Provisional, of 4/29/1998. Applicant admits on page 1 of the response filed 9/27/01 that SEQ ID NO's 4, 14, 27, 298, 311, 356, and 569 are not supported by the Provisional, therefore claims 1-2, 11, 13-15 and 17-20, which recite these sequences, are accorded priority only to the filing date of the instant application, of 4/28/1999.

Information Disclosure Statement

The IDS filed 5/1/02 has been fully considered.

35 U.S.C. 112, Written Description Rejection

Claims 1-2 and 10-21 are rejected, as previously set forth in the office actions of 12/20/00 and 12/4/01, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 5/1/02 have been fully considered but they are not persuasive. Applicant's arguments are addressed below.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description provisions of 35 USC 112, first paragraph. However, claims 1 and 2 recite open claim language (comprising) and claims 1 and 10 are specifically directed to encompass sequences that

hybridize to the claimed SEQ ID NO's. As the claims recite open claim language, they are also directed to encompass gene sequences, corresponding sequences from other species, mutated sequences, polymorphic sequences, exogenous sequences, and so forth, as set forth on pages 25-35 of the specification. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Applicant argues that a person of ordinary skill in the art, upon reading the specification, would understand that applicant had possession of the claimed SEQ ID NO's. Whether applicant had possession of sequences represented by the claimed SEQ ID NO's is not in dispute. As set forth above, sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description requirements. However, as set forth previously and reiterated above, the claims are directed to encompass sequences OTHER than those specifically described by the specification. While applicant is correct in that a claim may "comprise" sequences other than those specifically described by the specification, one skilled in the art must be able to readily envision members of the genus encompassed by the claim. As previously set forth, each claimed SEQ ID NO: is of insufficient length to encode a full-length enzyme. No complete ORF has been described by the specification which actually encodes an enzyme with the claimed enzymatic activity. SEQ ID NO: 1, for example, does not appear to contain a complete ORF, or to encode a complete protein sequence; i.e. it is merely a sequence "fragment."

As previously set forth, applicant has identified enzymes which are known in the prior art and have some sequence similarity to the claimed sequences. The sequences recited have not been shown to encode an entire enzyme, nor has any particular ORF been identified for the claimed sequences. Table A of the specification discloses sequence similarity information (e.g. % identity) between peptides putatively encoded by the claimed sequences and sequences which encode known enzymes. No comparison of binding regions, conserved regions, catalytic regions, etc. is shown to support that the peptides putatively encoded by the claimed SEQ ID NO's would be expected to actually exhibit ANY enzyme activity. As previously set forth, it is well known in the art that sequence similarity does not reliably correlate to structural and/or functional similarity. Applicant argues that it does, and cites several articles. VENTER merely teaches comparison of sequences to determine gene families. His "prediction" of function, like applicant's, is based on sequence similarities to proteins of known function (p.

1335). VENTER does not provide any support that sequence similarity alone is necessarily predictive of function. WOESE is directed to conservation of structure in rRNA's; it is not applicable to prediction of function of a *peptide* encoded by a cDNA or mRNA. A recent article documenting the unreliability of predicting structure and function based on sequence similarity is BAKER et al. (Science (10/5/2001), vol. 294, pages 93-96). Absent factual evidence to the contrary, one skilled in the art would reasonably doubt that sequence similarity alone is sufficient to predict whether the biological and enzymatic activity of the claimed subject matter is the same as that of the prior art. The specification fails to describe ANY nucleic acid actually encoding one or more of the claimed enzymes, therefore the rejection is maintained.

Applicant further argues that sequences either hybridize under the claimed conditions or they don't, and that the limitations with regard to hybridization fulfill the written description requirements as set forth in the Eli Lilly case. As set forth above, sequences may comprise noncoding regions or introns, but still hybridize to the claimed sequences. In response, it is noted that the rejection is made under lack of written description, not under lack of enablement (i.e. does the specification fully describe the invention, NOT does one skilled in the art know how to use it?) Genomic DNA is known to comprise introns, noncoding sequences, etc., such that a sequence which is much larger, and potentially encodes a variety of proteins, including those not described by the specification, could hybridize to the claimed sequence. Genomic DNA encompasses a large group of disparate sequences such that one skilled in the art would not be able to readily envision the plurality of sequences encompassed by the claim. While it is certainly within the ability of one skilled in the art to be able to determine whether a sequence hybridizes to one of the claimed SEQ ID NO's under the conditions recited in the claims, one skilled in the art would still not be able to readily envision members of the genus encompassed by the claims, and the rejection is maintained.

With the exception of sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required.

Claim 1 recites a "substantially purified nucleic acid" which encodes a "maize or soybean phosphogluconate pathway enzyme" wherein the nucleic acid is able to hybridize to specific SEQ ID NO's. The specification fails to describe any "substantially purified nucleic acid sequence" which is known to encode a maize or soybean phosphogluconate pathway enzyme. Once purified, nucleic acid and peptide sequences do not carry information with regard to their origin. An enzyme expressed from a nucleic acid will display activity, under appropriate conditions, no matter what system, cell line, clone, etc. it is expressed from/in. A purified sequence (comprising a complete ORF) may be cloned into another plant/cell line and a protein expressed; is the protein still a "maize or soybean" enzyme? In addition, it is noted that sequences which hybridize to one of the claimed nucleic acids under the conditions recited, and encode one of the recited enzymes, but are NOT sequences purified from maize or soybean are known in the art (see e.g. the sequence taught by MARTIN et al., below). As the specification fails to describe a "substantially purified nucleic acid" which encodes a "maize or soybean" enzyme, claim 1 is rejected for lack of written description.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1-2 are again rejected, as previously set forth in the office action of 12/4/01, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a nucleic acid molecule which hybridizes to a SEQ ID NO: from a recited list AND encodes a maize or soybean enzyme wherein the enzyme is one from a recited group. It is unclear whether applicant intends that any one of the SEQ ID NO's correlates with all of the recited enzymes, or intends for each SEQ ID NO: to correlate with a single enzyme. If the latter, then it is further unclear which SEQ ID NO: is intended to correlate with which enzyme. Applicant argues that one skilled in the art could easily ascertain whether or not a nucleic acid molecule comprises a nucleic acid as called for by the claim. Applicant is reminded that the rejection is made over a lack of clarity (are the metes and bounds of the claimed invention

clear?), and is not rejected under lack of enablement (would one skilled in the art know how to use the invention?) One skilled in the art could certainly ascertain whether a nucleic acid hybridizes to another, but without knowing which enzyme or enzymes the nucleic acid must also encode, would not know whether the nucleic acid is one encompassed by the claim. As it is not clear which enzyme, or enzymes, correlate(s) with which SEQ ID NO:, as previously set forth and reiterated above, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by NCBI accession number AF037030 (11/26/1998).

AF037030 teaches an mRNA/cDNA sequence which encodes a corn 6-phosphogluconate dehydrogenase and is 95% identical/complementary to instant SEQ ID NO: 4. A sequence which is 95% identical/complementary to SEQ ID NO: 14 would reasonably be expected by one skilled in the art to hybridize to SEQ ID NO: 14 or a complement of SEQ ID NO: 14 under the conditions recited in claims 1 and 10, therefore claims 1 and 1o are anticipated.

Applicant's arguments filed 5/1/02 have been fully considered but they are not persuasive. Applicant argues that as AF037030 is not identical to SEQ ID NO: 14. However, no degree of identity is recited in the claims. Applicant is reminded that claims 1 and 10 recite hybridization conditions; hybridization conditions do not "translate" into % identity limitations. Applicant further argues that no evidence has been set forth by the examiner that AF037030 would necessarily hybridize to SEQ ID NO: 14. The Office does not have the facilities to carry out hybridization experiments. The examiner maintains that one skilled in the art would reasonably expect a sequence with 95% identity/complementarity to SEQ ID NO: 14 to hybridize to SEQ ID NO: 14 or its complement. Applicant has not provided any evidence that a sequence which is 95% identical/complementary to SEQ ID NO: 14 would NOT hybridize to the complement of SEQ ID NO: 14 under the claimed hybridization conditions, therefore in the absence of evidence to the contrary, the examiner maintains the rejection. It is noted that claims 2 and 14, which are interpreted to recite sequences with 100% identity, are not rejected herein

Claim 10 is **newly** rejected under 35 U.S.C. 102(a) as being anticipated by UCHIMIYA (NCBI accession number D43256, 5/4/1998).

UCHIMIYA discloses a cDNA/mRNA sequence which is 74.6% identical/complementary to SEQ ID NO: 619. A sequence which is 74.6% identical/complementary to SEQ ID NO: 619 would reasonably be expected by one skilled in the art to hybridize to SEQ I DNO: 619 or its complement under the hybridization conditions recited in claim 10, therefore claim 10 is anticipated.

Claims 1 and 10 are **newly** rejected under 35 U.S.C. 102(a) as being anticipated by MARTIN et al. (NCI accession number AJ000265, 8/25/1998).

MARTIN teaches a sequence encoding glucose-6-phosphate isomerase which is 66.4% identical to SEQ ID NO: 619, with a local similarity of 79%. A sequence with 66.4% identity and a local identity/match of 79% would reasonably be expected by one skilled in the art to hybridize to the complement of SEQ ID NO: 619 under the hybridization conditions recited in the claims, therefore claims 1 and 10 are anticipated.

Claims 1 and 10 are **newly** rejected under 35 U.S.C. 102(b) as being anticipated by KATSURADA (NCBI accession number AB007907).

KATSURADA teaches a cDNA/mRNA which is encodes a soybean 6-phosphogulconate dehydrogenase and is 59.5% identical to SEQ ID NO: 27 with a local similarity to SEQ ID NO: 27 of 80.3%. A sequence with 59.5% identity and a local similarity of at least 80% would be reasonably expected by one skilled in the art to hybridize to SEQ ID NO: 27 or its complement under the conditions recited in the claims, therefore the claims are anticipated.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

July 15, 2002

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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